

A personalised exercise programme for individuals with lower limb amputation reduces falls and improves gait biomechanics: A block randomised controlled trial

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Background: Lower limb amputees (LLAs) are at increased risk of falling due to the inherent asymmetry resulting from their limb loss, muscle weakness and other neuro-musculoskeletal limitations.

Research question: The aim of this study was to evaluate the effects of a personalised exercise programme on falls prevention and gait parameters in LLAs.

Methods: Fifteen LLAs, recruited from their local prosthetic services centre, were block randomised, by age and level of amputation, into two groups: exercise group (transfemoral, n=5; transtibial, n=2) and control group (transfemoral, n=5; transtibial, n=3). The exercise group completed a 12-week programme, focusing on strength, balance, flexibility and walking endurance, delivered in group sessions at the University, and combined with a personalised home exercise programme. Temporal-spatial, 3D kinematic and kinetic gait parameters were collected at baseline and post-intervention. Falls incidence was also followed up at 12 months.

Results: The exercise group experienced significantly fewer falls in the one-year period from baseline, compared with the average annual falls rate, obtained at baseline ($P=0.020$; $d=1.54$). Gait speed in the exercise group increased by $0.21 \text{ m}\cdot\text{s}^{-1}$, to $0.98 \text{ m}\cdot\text{s}^{-1}$ ($P<0.001$; $d=0.91$), through increased intact limb cadence. In the pre-swing phase, there were significant increases in intact limb peak vertical force, and affected limb peak propulsive (anterior) force for the exercise group. Power absorption and generation significantly increased at both the intact and affected hip

joints (H3) and the intact ankle (A1 and A2) for the exercise group, resulting in significant group*time interactions.

Significance: This is the first study to document the clinically meaningful benefits of an exercise intervention for falls prevention and gait performance in LLAs.

Specialised exercise programmes for community-dwelling LLAs should be implemented as a method to reduce falls and improve walking performance in this population.

Keywords falls; lower limb amputee; exercise; gait; biomechanics

Introduction

Lower limb amputees (LLAs) have inherent musculoskeletal limitations as a result of their amputation. They have reduced strength in the residual limb, decreased range of motion (especially at prosthetic joints), slower comfortable gait speed, and present with gait asymmetries and impaired postural control^[1-4]. LLAs have an increased risk of falling compared with age-matched, able-bodied individuals. One study reported that 52% of LLAs fall annually, and 75% fall recurrently^[5]. These values likely underrepresent the problem, as many falls go unreported. Falls, and their consequences, present a significant cost for the healthcare system, and negative implications for quality of life.

Previous research documented biomechanical differences between transtibial amputee (TTA) fallers and non-fallers during level gait, including different ground reaction forces (GRFs) when the affected limb was transitioning into the more vulnerable, single support phase^[6]. Fallers also presented with different joint power profiles including less power absorption at the intact ankle in terminal stance (A1) and more power absorption at the intact hip in pre-swing (H2)^[6]. From these findings, evidence-based exercise recommendations were made for falls prevention in LLAs, based on the biomechanical profiles of non-fallers during level gait.

Recommendations included strengthening the affected knee extensors eccentrically to control knee flexion during loading, and increasing eccentric strength of the ankle plantarflexors and hip flexors on the intact limb^[6]. Enhanced eccentric strength could facilitate safer swing and foot placement of the affected limb by controlling tibial advancement over the intact stance limb, and safer weight transfer by controlling intact limb thigh deceleration during the initial, affected limb double support^[6].

However, these recommendations have yet to be validated.

Exercise programmes for falls prevention in older, able-bodied adults have demonstrated positive results including reducing falls incidence^[7], and the severity of injuries sustained from falls^[8]. Only a small number of previous studies have documented the effects of exercise in LLAs. These have included the benefits of a treadmill walking programme on temporal-spatial gait parameters in transfemoral amputees (TFAs)^[9], the short-term effects of a 3-day training programme during rehabilitation on 2-minute walk distance^[10], balance training for standing balance^[11] and the use of Wii Fit™ activities to maximise walking capacity^[12]. However, to the best of our knowledge, no studies have documented the effects of a multi-dimensional exercise intervention for preventing falls and maximising gait performance in LLAs.

Falls prevention guidelines^[13], endorsed by the British Association of Chartered Physiotherapists in Amputee Rehabilitation, advocate exercise as an important preventative measure against falls. However, these recommendations are supported by studies involving older, able-bodied individuals. As yet there is insufficient evidence to demonstrate the effects of exercise interventions to reduce falls in LLAs.

The aim of this study was to evaluate the effects of a 12-week supported exercise programme for LLAs on falls incidence and kinematic and kinetic gait parameters. It was hypothesised that participants in the exercise group would sustain fewer falls over a one-year period compared with the control group. It was also hypothesised that the exercise group would increase gait speed, and improve concentric and eccentric strength, evidenced through altered joint powers at the intact ankle and bilateral hip joints.

Methods

The study was a block randomised controlled trial. Ethical approval for this study was granted by the NHS local Research Ethics Committee (reference: 14/YH/1138).

Informed, written consent was obtained from each participant prior to study enrolment.

Participants

Participants were recruited from their local prosthetics centre. The centre manager screened all patients against the inclusion/exclusion criteria; those deemed eligible were sent information on the study and instructed to contact the research team.

Fifteen participants with lower limb amputation (TTA, n=5; TFA, n=10) were enrolled in the study between July 2015 and June 2016 (Figure 1). Participants were included in the study if they had a unilateral transtibial or transfemoral amputation for any reason, wore their prosthesis daily, and were able to ambulate independently along level surfaces with or without mobility aids. Participants were excluded if they had any chronic diseases, cardiac complications, uncontrolled asthma or diabetes, severe osteoporosis, or cognitive disorders. Participants currently engaged in structured exercise programmes were excluded. All participants had sustained a fall in the 2-year period prior to study enrolment, or were deemed at-risk by their multidisciplinary healthcare team.

Participants were block randomised according to age and level of amputation (exercise, n=7; control, n=8) by an independent researcher, following baseline assessments. A transfemoral level of amputation has been independently associated with greater falls risk in LLAs^[5].

Participant characteristics are presented in Table 1. The number of self-reported falls sustained in the two years prior to study enrolment was collected at baseline for each participant, and an average annual falls rate was determined. Falls history was also collected at a 12-month follow-up. A fall was defined as inadvertently coming to rest on the ground or other lower level.

Exercise intervention

Exercise group participants undertook a 12-week supported exercise intervention. Participants attended a supervised, circuit-style group exercise session twice weekly at the University, and completed personalised exercises at home once a week, progressing to twice-weekly from the mid-point of the intervention. Group and home exercises were multi-dimensional and designed to target gait endurance and speed (beyond their comfortable), flexibility (e.g., dynamic and static stretching of major muscle groups), strength (e.g., concentric/eccentric dynamic exercises such as squats, sit-ups, step-ups, calf raises, hip abduction, - with optional use of therabands, kettlebells or dumbbells), dynamic balance (e.g., picking up objects from the floor and balancing on a compliant surface) and cardiovascular fitness (cycle ergometer). A description of the exercises performed is detailed in Supplement 1, in line with the Consensus on Exercise Reporting Template^[14].

Data Collection

Participants wore their own tight-fitting clothing and normal, flat walking shoes. Twenty-nine retro-reflective markers (14mm) were placed bilaterally on the lower limbs and pelvis according to the six degrees-of-freedom (6DOF) marker set^[15]. For the affected limb, markers were placed in the equivalent locations on the prosthesis^[16]. Twenty-two markers were placed bilaterally on the head, trunk (xiphoid

process, sternal notch, acromion processes, lateral shoulders, C7 and T10 spinous processes, and inferior angle of the scapulae), lateral and medial humeral epicondyles, and radial and ulnar styloid processes. Clusters with four markers were placed bilaterally on the thigh, leg, upper and lower arms (total 32 markers).

Participants first completed a static calibration to identify joint centres. All markers on joint centres were removed bilaterally for the subsequent dynamic walking trials.

As part of the baseline and post-intervention assessments, ten Oqus motion capture cameras^(a) captured three-dimensional (3D) kinematic data at 100Hz using Qualisys Track Manager (QTM)^(b) and were synchronised with two Kistler force plates^(c) embedded in the floor sampling at 1000Hz. Participants completed ten trials along a 10-metre walkway, at their self-selected walking speed. Any trial where a participant did not make complete contact with the force plate, or adjusted their gait, was excluded completely from further analysis. At least six trials (range: 6-10 trials) were analysed for each participant.

Data Processing

Trials were analysed first in QTM, with identification of the marker coordinate data, and then exported to Visual 3D^(d). The 3D coordinate data were interpolated using a cubic-spline algorithm and low-pass filtered using a fourth order Butterworth filter, with a cut-off frequency of 6Hz for kinematic data. Force data were filtered with a 30Hz cut-off frequency. A full-body, thirteen segment, 6DOF model^[15] was built based on the static calibration file with bilateral virtual feet segments. We were unable to determine joint centres functionally due to the high risk of falling when performing the dynamic movements at the knee and/or hip joints. Joint moments and powers were calculated using inverse dynamic analysis. The X-Y-Z Cardan

sequence defined the order of rotations following the Right Hand Rule about the segment coordinate system axes. Gait events were identified in Visual 3D using an automatic event identification pipeline command, and were also checked manually. Participants completed the level gait task at two time points: baseline (PRE) and post-intervention (POST). Both assessments were repeated under exactly the same conditions, including participant's choice of usual flat footwear. Although some deterioration in footwear tread would have occurred in the 12 weeks between testing sessions, this was not quantified. The primary outcome measure was falls incidence. Secondary outcome measures included temporal-spatial parameters, peak sagittal and frontal plane joint angles, sagittal plane joint moments and powers labelled according to Eng and Winter (1995)^[17], and GRF data. Due to the combination of TTAs and TFAs in both groups, affected knee joint moments and powers were not analysed.

Statistical Analysis

Gait variables were imported into SPSS, Version 22^(e) for statistical analysis. An intention-to-treat analysis was performed. Missing values were imputed using multiple imputation^[18,19], five possible imputations were generated using a Markov chain Monte Carlo fully conditional specification. A repeated measures general linear model was used to assess for significant differences and interactions between, and within groups, across and at the two different time points, and to calculate 95% confidence intervals (CI). Null hypotheses were rejected when $P < 0.05$ and 95% CI did not include zero. Judgements regarding effect size were made using Cohen's d where < 0.41 was deemed negligible, > 1.15 as moderate and > 2.70 considered as a strong effect size^[20].

Results

No significant differences between groups for age, height, body mass and time since amputation were found (Table 1). Average attendance at the group exercise sessions was 83%, with a range of 75 to 96%.

Falls and temporal-spatial parameters

Falls data and temporal-spatial parameters are shown in Table 2. A significant reduction in the number of falls ($F_{(1,13)}=7.1$; 95% CI=1.1,10.7; $P=0.020$; $d=1.54$) was noted during the 12-month period from randomisation, compared with the average annual rate at baseline, for the exercise group. The exercise group also recorded significantly fewer falls than the control group during the 12-month follow-up period ($F_{(1,13)}=5.1$; 95% CI=-7.5,-0.2; $P=0.041$), with a significant group*time interaction ($F_{(1,13)}=7.9$; $P=0.015$).

The exercise group significantly increased walking speed by $0.21\text{m}\cdot\text{s}^{-1}$, to $0.98\text{m}\cdot\text{s}^{-1}$ ($F_{(1,13)}=3.8$; 95% CI=-0.3,-0.1; $P<0.001$, $d=0.91$). The exercise group significantly increased intact limb cadence ($F_{(1,13)}=3.8$; 95% CI=-23.9,-1.4; $P=0.030$; $d=0.89$). No significant differences were observed for step length, or stance and double support durations. There were significant group*time interactions for speed ($F_{(1,13)}=15.8$; $P=0.002$) and affected limb cadence ($F_{(1,13)}=4.9$; $P=0.047$) due to improvements in the exercise group, but no observed change in the control group.

Joint kinematics

Peak sagittal and hip frontal plane joint angles are presented in Table 2. There was a significant decrease in affected limb peak hip flexion angle for the exercise group in pre-swing ($F_{(1,13)}=8.3$; 95% CI=0.9,17.7; $P=0.033$; $d=0.98$), while significant increases were seen bilaterally for terminal stance peak hip extension angle, in the

exercise group (intact: $F_{(1,13)}=12.2$; 95% CI=-21.6,-4.5; $P=0.006$; $d=1.91$; affected: $F_{(1,13)}=15.8$; 95% CI=-22.2,-5.8; $P=0.003$; $d=1.64$).

Joint kinetics

Two control group participants were excluded from kinetic data analysis because of their short step length and multiple foot contacts with the same force plate. Peak GRFs, moments and powers are shown in Table 3. Joint powers are depicted graphically in Figure 2.

For the exercise group, the pre-swing, intact limb ankle plantarflexor moment significantly increased ($F_{(1,11)}=3.4$; 95% CI=-0.6,-0.1; $P=0.014$; $d=1.66$) (Table 3). At the hip, the affected limb eccentric (H2: $F_{(1,11)}=8.0$; 95% CI=0.01,0.7; $P=0.023$; $d=1.10$) and concentric powers (H3: $F_{(1,11)}=0.7$; 95% CI=-0.9,-0.2; $P=0.009$; $d=1.34$), combined with intact limb concentric power (H3: $F_{(1,11)}=4.0$; 95% CI=0.1,0.7; $P=0.023$; $d=1.20$), significantly increased for the exercise group. A significant group*time interaction was observed for affected limb H3 power generation ($F_{(1,11)}=11.9$; $P=0.005$). At the intact ankle A1 ($F_{(1,11)}=7.8$; 95% CI=0.01,0.6; $P=0.021$; $d=1.28$) and A2 ($F_{(1,11)}=18.3$; 95% CI=-1.8,-0.8; $P<0.001$; $d=2.97$) joint powers significantly increased, for the exercise group (Table 3), with a significant group*time interaction for power generation by the intact ankle plantarflexors (A2) ($F_{(1,11)}=14.8$; $P=0.003$).

Intact limb peak vertical GRF in pre-swing ($F_{(1,11)}=10.6$; 95% CI=-0.2,-0.03; $P=0.014$; $d=1.24$) and affected limb peak propulsive (anterior) GRF during push-off ($F_{(1,11)}=4.5$; 95% CI=-0.1,0.008; $P=0.015$; $d=1.00$) significantly increased for the exercise group.

Discussion

The aim of this study was to evaluate the effects of a 12-week personalised exercise programme on falls incidence and gait biomechanics. The findings are the first to demonstrate that a personalised exercise programme has the potential to reduce the number of falls sustained in a group of community-dwelling LLAs. Moreover, engaging in an exercise programme contributed to significantly faster walking speeds and increased joint power profiles at the intact ankle and bilateral hip joints.

There was a significant reduction in falls in the exercise group; six out of seven exercise group participants had fallen in the two years preceding study enrolment, with only one individual sustaining a fall in the one-year follow-up period. Although this was from a small group, the data were obtained from LLAs across a range of aetiologies, ages, genders and levels of amputation. The significant group*time interaction revealed that even a relatively short 12-week intervention can have positive effects for up to a year. Previous research with active, older able-bodied adults also demonstrated lasting effects, over a 12-month follow-up period^[21].

The reduction in falls from the exercise intervention has important implications for patient welfare and healthcare provision, as injuries and fatalities from falls result in a high economic cost^[22]. A reduction in falls may decrease the economic burden due to fewer visits to healthcare and/or prosthetic services, beneficial secondary effects such as increased balance confidence, less fear of falling and greater participation in daily and social activities may also be reported. Increased physical activity levels may contribute to the management of, or reduced risk of co-morbid conditions, in turn, also reducing demand on healthcare services. Previous research has shown that TFAs are at higher risk of falls^[5]; given this is inherently a non-modifiable risk

factor, our results are particularly encouraging with a large proportion of the exercise group being TFAs. While the indication for reduced falls incidence and changes in gait biomechanics are promising, it is important to conduct further research with a larger sample size, and with different eligibility criteria. Moreover, it would be important to undertake a cost-effectiveness analysis of running community-based exercise programmes by evaluating patient resource use, costs, and health outcomes associated with an exercise intervention. Potential benefits to LLAs may outweigh the costs associated with implementing community-based exercise programmes.

In the current study, walking speed increased in the exercise group as a function of cadence and not step length. The significant group*time interaction also suggests that the normal daily activities of the control group did not encourage faster walking in this study. Walking speeds for TTAs have been reported between 1.11 and 1.21m·s⁻¹^[16,23-25] whilst for TFAs, reported values range between 0.78 and 0.96m·s⁻¹^[23,26,27]. The baseline walking speeds observed in both groups were generally slow (near the lower speeds for TFAs) indicating that our participants were not functioning at high levels and therefore possibly more adaptable to exercise-related improvements given the opportunity. The significant increase in speed by 0.21m·s⁻¹ in the exercise group exceeded the minimal detectable change (MDC) of 0.10m·s⁻¹ for different populations of older adults^[28] and exceeded the substantial meaningful change of 0.13m·s⁻¹ for older adults with mobility difficulties^[29]. To the best of our knowledge, no established MDC for walking speed specifically for LLAs exists in the literature. However, we believe our results show clinically meaningful improvements in speed in the exercise group. The significantly increased bilateral hip extension was likely reflective of the increased walking speed in the exercise group, as faster

walking naturally extends the hip more^[30]. However, we are unable to understand the exact cause and effect relationship between the faster walking speed and gait variables (e.g., increased hip extension, hip joint powers) given the exercise programme was designed to incorporate elements of walking endurance and strength training.

The significant increase in intact limb peak vertical GRF (pre-swing) of the exercise group occurred when double support was ending, and single support was beginning on the affected limb. This change was likely reflective of the faster walking speed but may also suggest that the exercise group participants became more confident transitioning into the vulnerable single support phase on the affected side with enhanced dynamic stability. The significant increase in peak propulsive GRF (pre-swing) for the affected limb was more likely related to greater power at the ipsilateral hip rather than the prosthetic ankle itself. The ability to generate concentric hip flexor power on the affected side significantly increased, as demonstrated by hip power generation (H3) (i.e., hip flexor strategy). There was no significant change in affected ankle power generation at pre-swing (A2).

In the exercise group, intact limb power absorption in terminal stance (A1) significantly increased, with enhanced eccentric function of the ankle plantarflexors. Improved eccentric power of the hip flexor musculature on the affected side was also demonstrated by increased H2 power absorption. These findings partially validate previous recommendations^[6] that suggested improving eccentric strength at the intact ankle and hip joints, as larger joint powers were only observed at the intact ankle but not at the hip in the current study. Strength improvements in these muscle groups is important for controlling forward progression, foot placement and stability during locomotion, and consequently for falls prevention.

Increased concentric function of the intact ankle plantarflexors and hip flexors bilaterally was demonstrated through significant increases in A2 and H3 power generation bursts. However, in the control group there was a trend towards a decline in hip flexor concentric function (H3) on the affected side, with a moderate effect size ($P = 0.099$, $d=1.21$). In the absence of active plantarflexor power generation in pre-swing on the affected side, LLAs rely more on the hip flexor pull-off strategy to propel the affected limb into swing^[31]. Our significant group*time interaction for H3 power on the affected side (Table 3) indicated that the activities of daily living undertaken by the control group were probably insufficient for maintaining hip flexor concentric strength during this important phase in the gait cycle. Inadequate hip strength may place some LLAs at higher risk of tripping or falling if they fail to clear the ground sufficiently. Depending on the individual's prosthetic componentry, the hip musculature often compensates for the lack of active dorsiflexion and/or knee flexion at the prosthetic joints during the swing phase^[26].

Study limitations

Some limitations of this study must be acknowledged. The participants in the present study were a small cohort, and we were unable to block randomise according to all confounding factors that influence falls risk, such as time since amputation and previous falls history. The effects of footwear on prosthesis performance have been recognised^[32]. Although participants performed the biomechanical testing in the same shoes at baseline and 12-week follow-up post-intervention, the effects of tread and wear were not accounted for. This could have affected the kinetic profiles (compliance and energy return) of the prosthesis over time. We did not measure functional hip joint centres, because a static calibration was deemed safer in this population; however, this may result in inaccuracies in hip joint centre estimation of

the 3D model. Finally, the participants' activity levels were only measured for the duration of the intervention and not the 12-month follow-up; therefore, it is not possible to discern whether, and to what extent, physical activity or exercise participation during the follow-up period contributed to the change in falls incidence. Future studies should include long-term follow-up of physical activity levels post-intervention and consider using wearable activity monitors for this population.

Conclusions

This is the first study to document the benefits of a personalised exercise programme for falls prevention in LLAs. There were a reduced number of falls, and changes in gait including faster walking speeds, enhanced intact limb ankle function and bilateral hip function. These results show important, positive changes, as distal deficits from the amputation must come from proximal compensations. Future studies should emphasise personalised exercise programmes and account for individual's mobility goals.

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Suppliers

- a. Oqus 400, Qualisys, Kvarnbergsgatan 2, 411 05, Gothenburg, Sweden
- b. Qualisys Track Manager, Version 2.11, Qualisys, Kvarnbergsgatan 2, 411 05, Gothenburg, Sweden
- c. Model 9286AA, Kistler, Eulachstrasse 22, 8408, Winterthur, Switzerland
- d. C-Motion, 20030 Century Boulevard, Suite 104A, Germantown, Maryland, 20874, USA
- e. Version 22, SPSS, International Business Machines Corp. (IBM), New Orchard Road, Armonk, New York, 10504, USA

Table 1. Mean (SD) participant demographics and details of prosthetic componentry.

	Gender	Age (years)	Height (cm)	Body mass (kg)	Time since amputation (years)	Level of amputation	Reason for amputation	Prosthetic knee	Prosthetic ankle
Exercise group									
1	F	50	166	101	3	Transfemoral	Malignancy	Polycentric, Steeper	SACH, College Park
2	M	78	176	91	1	Transtibial	Vascular	---	SACH, Streifeneder
3	F	68	163	66	49	Transtibial	Trauma	---	Multi-axial, Blatchford
4	M	65	170	93	7	Transfemoral	Vascular	Polycentric, Ottobock	SACH, Streifeneder
5	M	63	182	106	8	Transfemoral	Infection	Microprocessor, Ottobock	Dynamic, Ottobock
6	F	52	159	81	3	Transfemoral	Malignancy	Monocentric, Steeper	SACH, College Park
7	M	42	185	109	0.8	Transfemoral	Vascular	Polycentric, Steeper	Energy-returning, Freedom Innovations
Mean (SD):		60 (12)	172 (10)	92 (15)	10 (17)				
Control group									
1	M	61	179	82	1	Transfemoral	Vascular	Monocentric, Steeper	SACH, College Park
2	M	64	178	81	48	Transfemoral	Trauma	Polycentric, Steeper	SACH, College Park
3	M	60	177	113	4	Transfemoral	Infection	Monocentric, Steeper	SACH, College Park
4	F	79	146	54	30	Transtibial	Trauma	---	SACH, College Park
5	M	34	191	124	10	Transtibial	Trauma	---	Dynamic, Trulife
6	M	91	167	92	12	Transtibial	Vascular	---	Multi-axial, Blatchford
7	M	64	176	129	0.6	Transfemoral	Osteomyelitis	Polycentric, Blatchford	SACH, College Park
8	M	66	179	84	47	Transfemoral	Trauma	Polycentric, Össur	Dynamic, College Park
Mean (SD):		65 (16)	174 (13)	95 (25)	19 (20)				

Table 2. Mean (SD) falls, temporal-spatial and kinematic results. Peak joint angles are shown in degrees (°). 95% confidence intervals (CI) are shown. Exercise, n=7; control, n=8.

	Exercise					Control				
	Baseline	12-months	CI	P	d	Baseline	12-months	CI	P	d
Falls (n) [†]	6.1 (7.4)	0.1 (0.4)	1.1, 10.7	0.020*	1.54	1.4 (1.2)	4.0 (4.8)	-7.1, 1.9	0.230	0.87
	PRE	POST	CI	P	d	PRE	POST	CI	P	d
Gait Speed (m·s ⁻¹) [†]	0.77 (0.25)	0.98 (0.21)	-0.31, -0.12	<0.001*	0.91	0.84 (0.31)	0.82 (0.28)	-0.65, 0.11	0.586	0.07
Double Support (%)	31.4 (7.0)	27.0 (3.7)	-0.3, 9.0	0.066	0.82	30.9 (9.8)	30.1 (6.5)	-3.6, 5.2	0.699	0.10
Step length (m)										
Intact	0.52 (0.13)	0.52 (0.14)	-0.11, 0.12	0.938	0.00	0.52 (0.17)	0.53 (0.14)	-0.11, 0.10	0.935	0.06
Affected	0.55 (0.10)	0.62 (0.14)	-0.19, 0.05	0.211	0.58	0.57 (0.16)	0.60 (0.16)	-0.14, 0.08	0.537	0.19
Cadence (steps/min)										
Intact	97 (20)	109 (8)	-24, -1	0.030	0.96	99 (10)	102 (8)	-13, 8	0.566	0.33
Affected [†]	78 (16)	88 (16)	-21, 1	0.068	0.63	87 (16)	82 (12)	-5, 15	0.302	0.36
Stance (%)										
Intact	71.3 (5.7)	68.6 (4.8)	-0.3, 5.7	0.070	0.51	66.1 (6.9)	67.3 (5.2)	-4.0, 1.6	0.358	0.20
Affected	59.7 (2.0)	56.4 (3.2)	-7.8, 14.5	0.527	1.27	60.3 (6.4)	53.8 (13.4)	-3.9, 16.9	0.201	0.66
Peak hip adduction (pre-swing)										
Intact	-0.66 (4.90)	-0.34 (5.68)	-6.49, 5.84	0.911	0.06	0.99 (7.55)	5.33 (3.82)	-10.10, 1.44	0.129	0.76
Affected	-7.19 (7.13)	-6.15 (4.70)	-7.41, 5.32	0.729	0.18	-5.16 (1.59)	-3.72 (4.60)	-7.39, 4.51	0.609	0.47
Peak hip abduction (swing)										
Intact	9.69 (3.67)	9.23 (6.92)	-5.48, 6.40	0.869	0.09	11.85 (7.35)	14.69 (4.27)	-8.40, 2.71	0.289	0.49
Affected	4.69 (7.42)	5.16 (6.69)	-7.37, 6.39	0.884	0.07	3.54 (3.49)	6.66 (6.73)	-9.53, 3.31	0.314	0.61
Peak hip extension (terminal stance)										
Intact	-9.2 (9.1)	-22.2 (4.5)	4.5, 21.6	0.006*	1.91	-12.8 (10.0)	-18.6 (6.7)	-2.1, 13.8	0.138	0.7
Affected	-9.5 (14.0)	-23.5 (3.1)	5.8, 22.2	0.003*	1.64	-12.9 (7.9)	-19.6 (6.5)	-1.0, 14.3	0.085	0.92
Peak hip flexion (swing)										
Intact	27.2 (11.6)	22.1 (5.2)	-3.3, 13.5	0.214	0.61	25.2 (5.0)	24.5 (6.3)	-7.2, 8.6	0.85	0.12
Affected	28.3 (12.3)	19.0 (6.6)	0.9, 17.7	0.033*	0.98	25.2 (10.3)	19.2 (8.3)	-1.9, 13.9	0.123	0.65
Peak knee flexion (loading response)										
Intact	4.0 (7.3)	7.5 (9.2)	-8.8, 1.8	0.177	0.42	13.1 (8.5)	13.2 (3.2)	-5.0, 4.8	0.962	0.02
Affected	0.8 (8.7)	1.7 (10.0)	-7.3, 5.5	0.760	0.10	6.1 (9.5)	3.1 (12.3)	-3.0, 9.0	0.301	0.27
Peak knee flexion (swing)										
Intact	56.7 (6.5)	63.7 (4.0)	-19.6, 5.7	0.254	1.33	51.9 (19.9)	63.8 (3.9)	-23.8, -0.1	0.049*	1.00
Affected	40.3 (20.6)	49.4 (14.8)	-19.9, 1.8	0.094	0.51	49.4 (23.3)	44.9 (24.3)	-5.6, 14.6	0.355	0.19
Peak dorsiflexion (terminal stance)										
Intact	17.0 (3.5)	17.8 (2.7)	-3.8, 2.2	0.579	0.26	15.6 (6.0)	17.2 (4.0)	-4.5, 1.2	0.237	0.32
Affected	14.5 (6.4)	11.0 (4.2)	-0.6, 7.5	0.092	0.66	10.8 (3.8)	11.6 (4.9)	-4.6, 3.0	0.651	0.18
Peak plantarflexion (pre-swing)										
Intact	-12.2 (5.2)	-14.3 (2.8)	-3.3, 7.5	0.414	0.53	-8.2 (9.7)	-11.3 (7.9)	-1.9, 8.1	0.206	0.35
Affected	-9.9 (7.0)	-2.8 (3.5)	-12.2, -2.0	0.010*	1.35	-2.7 (4.1)	-2.4 (5.0)	-5.0, 4.6	0.920	0.07

Grey boxes indicate: † denotes a statistically significant ($P < 0.05$) group*time interaction. * denotes a statistically significant within-group change.

Table 3. Mean (SD) GRF (N/kg), peak joint moment (Nm/kg) and joint power (W/kg) data. Affected knee joint powers and moments were not analysed due to a combination of TTAs and TFAs within both groups. The intact knee did not demonstrate a discernible K2 power burst and therefore K2 is not reported. 95% confidence intervals (CI) are shown. Exercise, n=7; control, n=6.

	Exercise Group					Control Group				
	PRE	POST	CI	P	d	PRE	POST	CI	P	d
Peak vertical GRF (loading response)										
Intact	0.97 (0.14)	1.05 (0.16)	-0.19, 0.03	0.133	0.53	0.98 (0.09)	1.08 (0.16)	-0.21, 0.02	0.096	0.80
Affected	1.01 (0.13)	1.01 (0.16)	-0.13, 0.13	0.985	0.00	0.94 (0.12)	0.95 (0.10)	-0.15, 0.13	0.876	0.09
Peak vertical GRF (pre-swing)										
Intact	0.93 (0.09)	1.06 (0.12)	-0.24, -0.03	0.014*	1.24	1.02 (0.08)	1.11 (0.15)	-0.20, 0.02	0.109	0.78
Affected	0.95 (0.07)	0.90 (0.09)	-0.05, 0.14	0.288	0.62	0.88 (0.10)	0.90 (0.14)	-0.12, 0.08	0.657	0.17
Peak braking force (loading response)										
Intact	-0.12 (0.07)	-0.16 (0.06)	-0.00, 0.08	0.059	0.62	-0.15 (0.07)	-0.17 (0.06)	-0.03, 0.07	0.351	0.31
Affected	-0.09 (0.05)	-0.10 (0.05)	-0.03, 0.05	0.659	0.20	-0.10 (0.04)	-0.09 (0.07)	-0.05, 0.04	0.701	0.25
Peak propulsive force (pre-swing)										
Intact	0.17 (0.04)	0.20 (0.04)	-0.07, 0.02	0.268	0.75	0.18 (0.09)	0.17 (0.09)	-0.04, 0.06	0.626	0.11
Affected	0.05 (0.04)	0.09 (0.04)	-0.06, 0.01	0.015*	1.00	0.09 (0.05)	0.09 (0.04)	-0.03, 0.03	0.811	0.00
Hip extensor moment (loading response)										
Intact	0.42 (0.26)	0.61 (0.22)	-0.45, 0.09	0.166	0.79	0.55 (0.40)	0.75 (0.24)	-0.50, 0.09	0.148	0.63
Affected	0.28 (0.48)	0.52 (0.23)	-0.29, 0.16	0.527	0.68	0.47 (0.08)	0.52 (0.23)	-0.30, 0.19	0.613	0.32
Hip flexor moment (terminal stance)										
Intact	-0.65 (0.19)	-0.73 (0.27)	-0.17, 0.33	0.493	0.35	-0.66 (0.31)	-0.60 (0.25)	-0.32, 0.22	0.676	0.21
Affected	-0.64 (0.21)	-0.81 (0.23)	-0.10, 0.44	0.201	0.77	-0.56 (0.30)	-0.38 (0.26)	-0.48, 0.11	0.186	0.64
Hip extensor moment (swing)										
Intact	0.41 (0.13)	0.46 (0.16)	-0.14, 0.04	0.211	0.34	0.31 (0.10)	0.30 (0.11)	-0.09, 0.11	0.793	0.10
Affected [†]	0.24 (0.04)	0.29 (0.10)	-0.12, 0.18	0.130	0.71	0.43 (0.13)	0.37 (0.14)	-0.01, 0.14	0.101	0.44
Knee extensor moment (loading response)										
Intact	0.07 (0.31)	0.25 (0.30)	-0.47, 0.11	0.209	0.59	0.37 (0.36)	0.18 (0.17)	-0.12, 0.50	0.208	0.72
Affected	---	---	---	---	---	---	---	---	---	---
Knee flexor moment (terminal stance)										
Intact	-0.22 (0.19)	-0.23 (0.14)	-0.22, 0.23	0.959	0.06	-0.25 (0.22)	-0.38 (0.34)	-0.12, 0.37	0.272	0.46
Affected	---	---	---	---	---	---	---	---	---	---
Knee extensor moment (pre-swing)										
Intact	0.13 (0.23)	0.09 (0.08)	-0.10, 0.19	0.506	0.26	0.07 (0.07)	0.05 (0.03)	-0.13, 0.17	0.804	0.40
Affected	---	---	---	---	---	---	---	---	---	---
Ankle plantarflexor moment (pre-swing)										
Intact	0.99 (0.28)	1.33 (0.13)	-0.60, -0.08	0.014*	1.66	1.21 (0.16)	1.27 (0.24)	0.34, 0.22	0.654	0.30
Affected	1.10 (0.35)	1.08 (0.39)	-0.20, 0.23	0.874	0.05	1.19 (0.41)	1.10 (0.40)	0.13, 0.33	0.368	0.22
H1										
Intact	0.36 (0.38)	0.58 (0.34)	-0.60, 0.17	0.251	0.61	0.18 (0.48)	0.64 (0.32)	-0.88, -0.04	0.033*	1.15
Affected	0.49 (0.94)	0.16 (0.45)	-0.10, 0.78	0.119	0.47	0.49 (0.19)	0.30 (0.37)	-0.29, 0.67	0.402	0.68
H2										
Intact	-0.39 (0.20)	-0.46 (0.29)	-0.15, 0.28	0.497	0.29	-0.52 (0.36)	-0.45 (0.29)	-0.30, 0.17	0.552	0.22
Affected	-0.35 (0.21)	-0.74 (0.50)	0.07, 0.72	0.023*	1.10	-0.57 (0.69)	-0.79 (0.55)	-0.13, 0.58	0.190	0.35
H3										
Intact	0.60 (0.33)	0.99 (0.32)	-0.72, -0.07	0.023*	1.20	0.70 (0.34)	0.74 (0.35)	-0.40, 0.31	0.796	0.12
Affected [†]	0.36 (0.19)	0.87 (0.57)	-0.86, -0.15	0.009*	1.34	0.72 (0.30)	0.40 (0.23)	-0.07, 0.70	0.099	1.21
K1										
Intact	-0.25 (0.35)	-0.36 (0.35)	-0.62, 0.84	0.743	0.31	-0.73 (1.40)	-0.36 (0.26)	-1.16, 0.41	0.317	0.45
Affected	---	---	---	---	---	---	---	---	---	---
K3										
Intact	-0.50 (0.53)	-0.38 (0.31)	-0.31, 0.08	0.222	0.29	-0.42 (0.26)	-0.41 (0.18)	-0.22, 0.20	0.928	0.05
Affected	---	---	---	---	---	---	---	---	---	---
K4										
Intact	-1.20 (0.52)	-1.51 (0.69)	-0.07, 0.69	0.099	0.51	-0.74 (0.46)	-1.03 (0.54)	-0.12, 0.70	0.148	0.58
Affected	---	---	---	---	---	---	---	---	---	---
A1										
Intact	-0.56 (0.22)	-0.86 (0.25)	0.06, 0.56	0.021*	1.28	-0.63 (0.19)	-0.79 (0.07)	-0.11, 0.43	0.217	1.23
Affected	-0.51 (0.29)	-0.67 (0.26)	-0.06, 0.38	0.127	0.58	-0.62 (0.35)	-0.63 (0.31)	-0.22, 0.25	0.871	0.03
A2										
Intact [†]	1.49 (0.60)	2.81 (0.29)	-1.80, -0.83	<0.001*	2.97	1.72 (0.60)	1.79 (0.75)	-0.59, 0.45	0.772	0.10
Affected	0.48 (0.29)	0.50 (0.27)	-0.31, 0.27	0.868	0.07	0.81 (0.52)	0.65 (0.39)	-0.15, 0.47	0.280	0.35

† denotes a statistically significant (P<0.05) group*time interaction. * denotes a statistically significant within-group change.

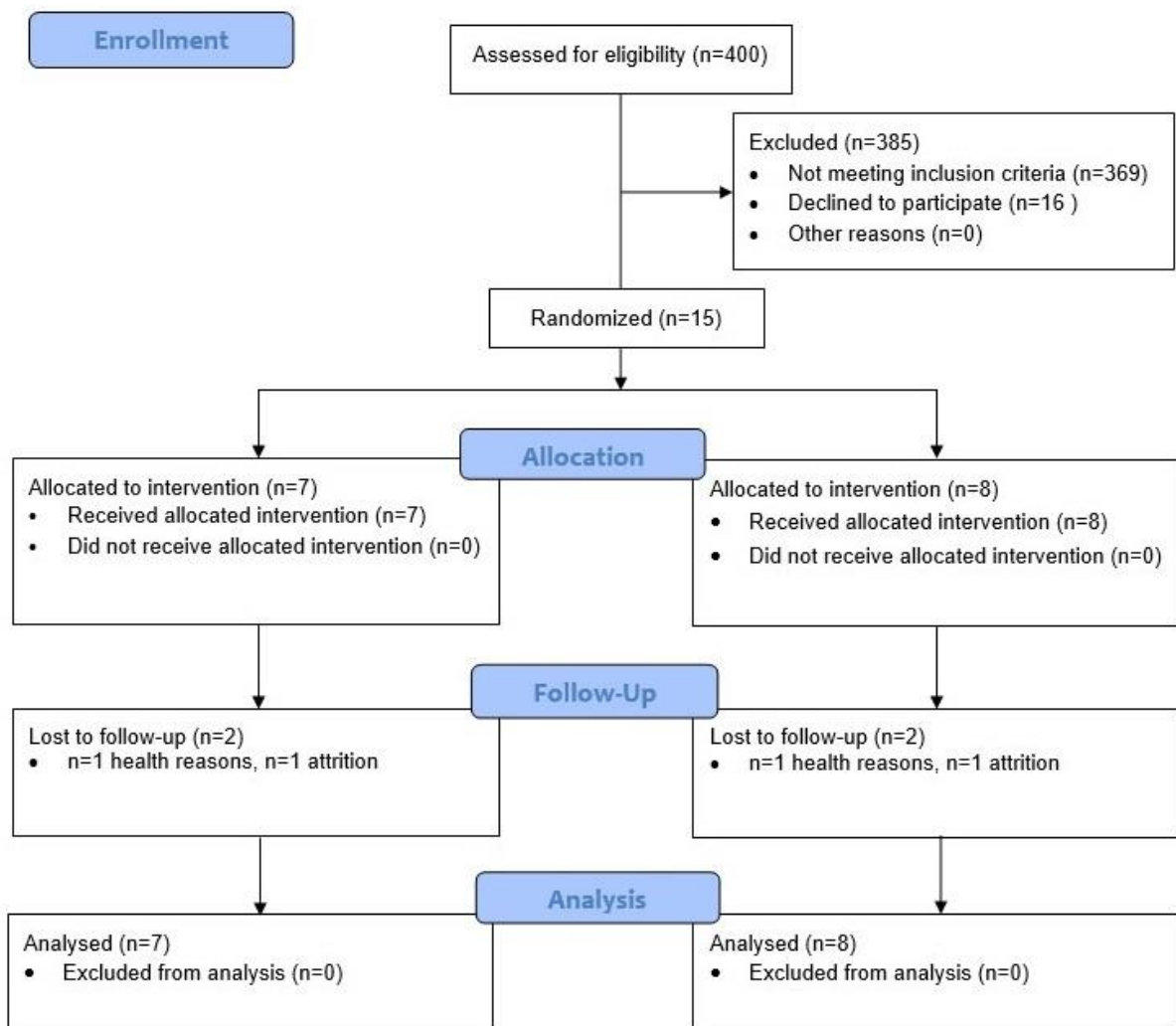


Fig. 1. CONSORT flow diagram for this study.

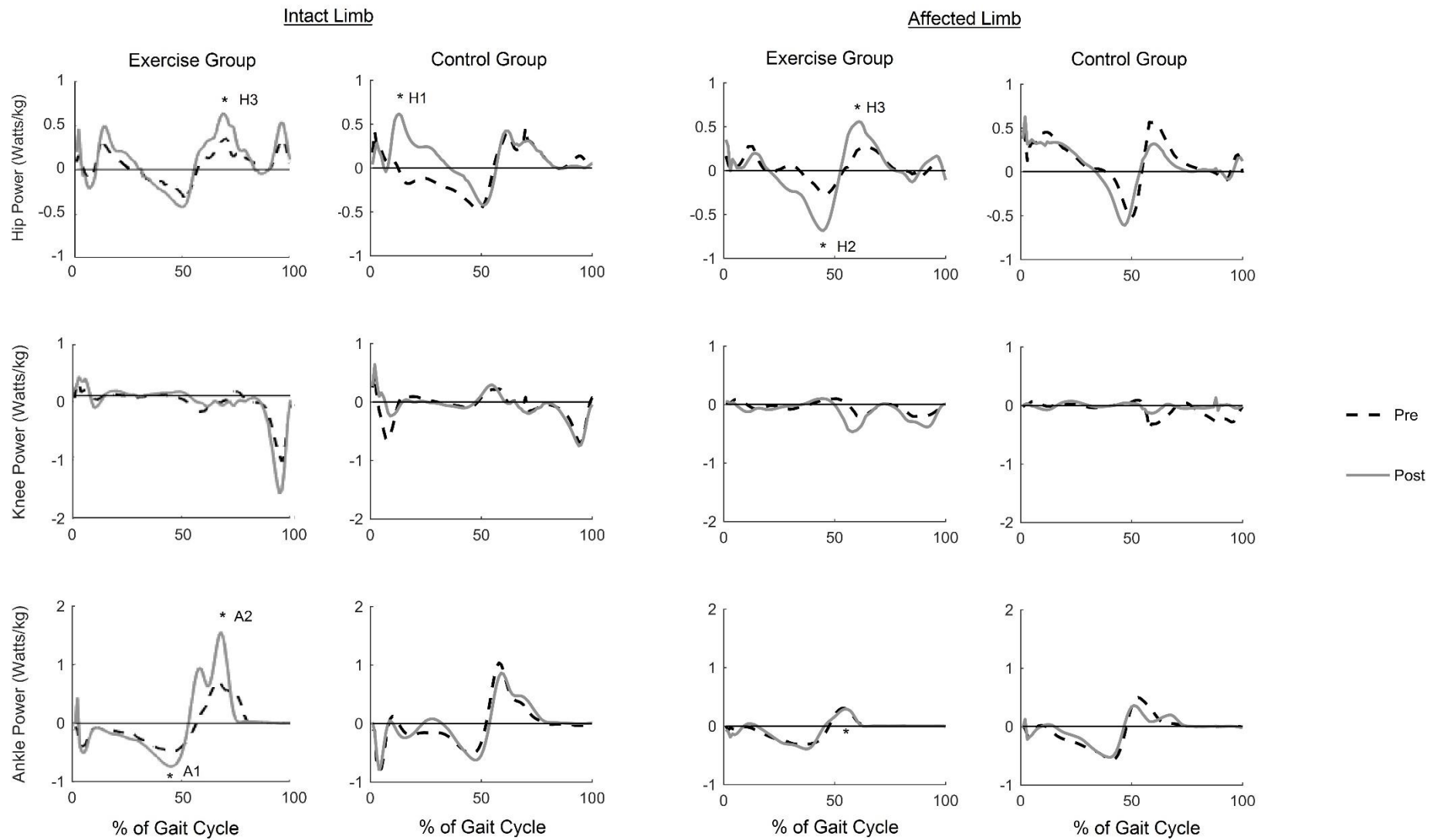


Fig 2. Sagittal plane joint powers (W/kg) for the exercise and control groups at pre-and post-intervention. Positive values indicate

power generation (concentric contraction); negative values indicate power absorption (eccentric contraction).

* denotes statistically significant ($P < 0.05$) within-group differences; H1: power generation by the hip extensors; H2: power absorption by the hip flexors; H3: power generation by the hip flexors; A1: power absorption by the ankle plantarflexors; A2: power generation by the ankle plantarflexors.

Supplement 1: Consensus on Exercise Reporting Template (CERT)

WHAT: Materials

Exercise equipment available to participants is outlined in Table 1.

Table 1. Exercise equipment used throughout the intervention

Exercise Equipment (Item 1)
Kettlebells increasing in 4kg increments, ranging from 4kg to 20kg ^a
Dumbbells (pairs) increasing in 2kg increments, ranging from 4kg to 40kg ^b individually
Weighted medicine balls at 4kg, 6kg and 8kg ^c
Double handled weighted medicine balls at 6kg, 8kg, and 10kg ^d
Box steps (adjustable to heights of 13cm, 15cm, 17.5cm, 20cm and 25cm) ^{e,f}
Bean bags
Ankle weights (pairs) at 1kg, 1.5kg, 2kg and 2.5kg individually ^e
Bicycle ergometer ^g
Hedgehogs balance discs (half circle discs) ^h
Standard chairs
Standard yoga mat
Swiss Balls (diameters of 55cm and 75cm) ^h
Thera-bands of varying resistance ⁱ

WHO: Provider

The exercise instructor had completed the Level 3 Exercise for Disabled Clients, Level 3 Exercise Referrals, and Level 3 Exercise for Older Adults courses and had 22 years' experience. The exercise instructor was assisted in supervision by the lead researcher, who had completed a BSc (Hons) Sport Rehabilitation, and had 3 years' experience instructing exercise. (Item 2)

HOW: Delivery

Participants attended the exercise session that took place at the University as a group session of up to five. However, all participants completed each exercise individually. The home-exercise programme was individual. (Item 3)

The group exercise sessions at the University were supervised and delivered as a circuit-style class. Each station was signposted with the name/type of exercise and key instructions to remember. The home-exercise programme was unsupervised. Participants were each provided with written instructions and images of each exercise in addition to prescribed sets and repetitions. Prior to doing the exercises at home, each participant was given a demonstration of each exercise by the lead researcher and asked to perform it themselves under supervision. (Item 4)

Attendance was taken for each of the exercise classes and is reported as a percentage attended of the 23 possible sessions during the intervention period. One group session was replaced with a home-exercise session due to a public holiday, for a total of 23 sessions. No specific strategies were used to measure adherence to exercise in the group-based sessions, however as there was no more than five participants in an exercise session, and two supervisors, this was not considered an issue as participants were closely supervised at all times. (Item 5)

No motivation strategies were included in this intervention. (Item 6)

Progression of individual exercises was participant-led, and participants were directed to increase speed, weight or difficulty when they felt ready to do so. The only exception to this was the increase in station duration from 60 seconds to 90 seconds after three weeks of the intervention. The exercise programme overall was progressed by increasing the number of different stations. In week one only four stations were used, with the remaining stations implemented regularly throughout the intervention. Furthermore, the recovery periods between stations was gradually decreased from 90 seconds at the beginning of the intervention period to 30 seconds at the end. (Items 7a, 7b)

The warm-up for each session consisted of mobility exercises for all joints in the body, by moving through the available range of movement. This was performed seated and standing. Participants then performed walking exercises to raise their heart rate, which consisted of marching on the spot, and taking steps forwards, backwards, left and right. The duration of the walking exercise was slowly extended throughout the duration of the intervention as the participants became more accustomed. Following the walking exercises participants completed a stretching programme for the major muscle groups in the body. A description of each exercise station used throughout the intervention period is provided in Table 2.

Table 2. Exercises used throughout the intervention period.

Exercise
Kneeing a Swiss ball in the air, alternating legs (advanced alternative: step ups)
Holding a medicine ball and twisting from side to side
Seated stomach crunches with a medicine ball
Brisk walk in a large unencumbered space (with the use of mobility aids if needed)
Squats over a chair (alternatives: standing active hip extension or performing squats whilst holding onto a fixed bar in front)
Prone lying back extension
Side lying hip abduction (option of adding ankle weights)
Side lying hip adduction (option of adding ankle weights)
Side stepping (10 steps each way)
Single leg calf raises whilst holding onto a bar at chest height
Balancing on a compliant surface (half circle discs, Senso Hedgehog Balance Disc, TOGU, Germany)
Walking along 10m walkway and picking up bean bags on the floor located at regular intervals
Step ups using a box step placed between metal bars fixed to the ground
Stationary cycling

The cool down for each session consisted of light walking for one minute followed by stretching of all major muscle groups. (Item 8)

All exercise group participants received an individualised home-exercise programme.

The home exercises were individualised based on results from baseline testing for

strength, postural control, balance, level gait, stair walking, range of motion and from answers to four psychometric questionnaires: Houghton Scale of Prosthetic Confidence⁽¹⁾, Activities-specific Balance Confidence Scale⁽²⁾, Locomotor Capabilities Index-5⁽³⁾ and the Short form-36⁽⁴⁾. The Activities-specific Balance Confidence Scale has been validated for use with lower limb amputees⁽⁵⁾. All participants received one strengthening exercise, one balance exercise, one flexibility exercise, one cardiovascular fitness exercise and then two further exercises from the categories above according to their individual profile. A detailed description of exercises prescribed as part of the home-exercise programme is provided in Table 3. (Item 9)

Table 3. List of all total exercises prescribed for the home exercise programme, participants received six exercises based on their personal profile from baseline testing.

Exercise
Step-ups using box step or step from garden to the house using doorframe for support
Quadriceps stretching (prone)
Unilateral calf raises
Standing hip extension
Prone lying hip extension
Side-lying hip abduction and adduction
Prone lying back extension
Abs crunches in crook lying
Walking heel-to-toe
Squats over a chair
Brisk walking
Shifting weight from the left to the right foot and standing on each leg for five seconds
Sideways walking
Sitting knee extension
Stair walking
Supine lying hip flexor stretching
Picking up objects off the ground in a clear open space

There were no non-exercise components to this intervention. (Item 10)

There were no adverse events that occurred during the exercise regime, or throughout the entire study intervention. (Item 11)

WHERE: Location

The group-based exercise session took place in a University sports laboratory setting. Home-based exercises were completed in the participants' own homes. (Item 12)

WHEN, HOW MUCH: Dosage

The exercise intervention had a duration of 12 weeks. Two group-based sessions were held each week, with 23 sessions in total (the supervised session was replaced by a home-exercise session one week only due to a public holiday). Each group-based session lasted one hour in total, including warm-up and cool down. For the first three weeks of the intervention each exercise station within the session lasted for 60 seconds, participants were asked to perform the exercise at a self-selected comfortable pace for themselves. For the remaining nine weeks each exercise station had a duration of 90 seconds, and the number of repetitions was determined by the selected pace of the individual participant.

In the first week a total of four different stations was completed once by participants (total: 4). In the second week, participants completed five different stations twice (total: 10). In weeks three and four, participants completed six different stations twice (total: 12). In weeks five and six, participants completed seven different stations twice (total: 14). In week seven, participants completed eight different stations, and completed 14 stations in a session. In weeks eight and nine, participants completed 10 different stations, and completed 14 stations in a session. In weeks 10, 11, 12,

participants completed 13 different stations and completed a total of 15, 16 and 17 stations, respectively. (Item 13)

The home-based programme was implemented after completion of two weeks of the intervention period. The staggered implementation of the two aspects was designed to allow participants and researchers learn how each individual's body reacted to the increase in physical activity and exercise. Participants completed the home-based exercise programme once per week from week three to the end of week seven of the intervention. The home-based exercises were then reassessed and a modified home-based programme was provided to participants to complete twice per week for the remaining five weeks of the intervention. In total, participants completed the home-based programme for 10 of the 12 weeks of the intervention period.

TAILORING: What, how

The exercises in both the group- and home-based sessions were tailored to the individual. Participant-led changes included the pace at which the exercises were performed and the weight or height added, where appropriate. (Items 14a, 14b)

Starting levels were ascertained through analysis of the biomechanical testing undertaken, and through subsequent discussion between the participant and instructors to determine expertise and previous experience. The entry-level and progression differed for each exercise. Therefore, and due to the participant-led and personalised nature of this exercise intervention, these levels were not given titles such as beginner, etc. (Item 15)

Participation in the home-based exercises was reported in the PASE, and attendance was measured in the group-based sessions. No specific adherence strategies were used. It is a recommendation of this article that future studies

consider the use of activity monitors to enable closer monitoring of participation, particularly of the home-based programme and activities external to the structured exercise intervention. (Item 16a)

The exercise intervention was delivered predominantly as planned. The main issues encountered were attendance (although this was 83% on average and consistent with an intervention in a similar group of participants⁽⁶⁾) and alterations to exercise due to limitations or problems experienced with the prosthesis (i.e. good prosthetic fit when sweating). (Item 16b)

References

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Equipment suppliers

- a. Eleiko Group AB, Korsvägen 31, SE-30256, Halmstad, Sweden
- b. Pioneer, Pullum Sports, 2 Greaves Way, Stanbridge Industrial Estate, Leighton Buzzard, Bedfordshire, LU7 4UB, England
- c Britannia Boxing Equipment (BBE) Boxing, York Way, Daventry, Northamptonshire, NN11 4YB, England
- d. York Fitness, York Way, High March Industrial Estate, Daventry, Northamptonshire, NN11 4YB, England
- e. Performance Health, Patterson Medical Limited, Nunn Brook Road, Huthwaite, Sutton-in-Ashfield, Nottinghamshire, NG17 2HU, England
- f. adidas AG, Adi-Dassler-Strasse 1, 91704 Herzogenaurach, Germany
- g. daum electronic GmbH, Flugplatzstr. 100, D-90768, Fürth, Germany
- h. TOGU GmbH, Atzinger Str. 1, 83209 Prien-Bacham, Germany.
- i. TheraBand, 1245 Home Avenue, Akron, Ohio, 44310, USA